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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/600,812  
Filing Date: June 20, 2003  
Appellant(s): BONADIO ET AL.

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Thomas Y. Ho  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 04/2009 appealing from the Office action mailed March 3<sup>rd</sup>, 2009.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The Board issued a judgment in Patent Interference No. 104,195 on August 15, 2001.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 73-85, 87-100, 106 and 107 are pending and finally rejected.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

5,640,977

Leahy

6-1997

Patent Interference No. 104,195 Decision Rendered August 15, 2001.
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**(9) Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

**Claims 106, 107, 73-85, and 87-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended include limitations added, in the amendment filed 5/5/08, that are not supported by the original disclosure. New claims 106 & 107 now recite limitations that do not have support in the originally filed disclosure. While Applicant has pointed to page 9, line 27 through page 10, line 4 and Figure 9 of the specification and drawings for the support of the new claim limitations, the examiner disagrees that these eleven lines & Figure 9 can be interpreted to provide support for the following structures & claimed functions:

In claims 106, the limitation of an entry seal assembly located ***such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases in pressure within the controlled pressurized environment*** is not supported.

In claim 107, the limitation of the engagement of the distal ring to the internal body tissue providing ***a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment*** is not supported.

With respect to dependent claims 73-85 and 87-100, they are rejected under 35 U.S.C. 112, first paragraph, insofar as they are dependent in some fashion from claims 105-110 and therefore incorporate the deficiencies noted above.

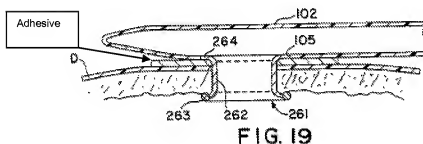
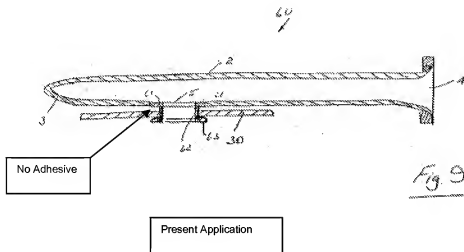
***Claim Rejections - 35 USC § 102***

**Claims 73-85, 87-100, 106 & 107 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Leahy (U.S. Patent No. 5,640,977).** Leahy anticipates the claimed invention because of admissions made by Appellant during an interference proceeding, during an Examiner's Interview on March 23, 2005 and given the fact that Leahy was declared the winning party of the interference. Also, please note the previous arguments in the Non-final dated 11/05/07 regarding Leahy (US 5,640,977) as they apply to the claimed invention.

During the interview on March 23, Appellant and his attorney made the following admissions:

1) The new claims 73-85, 87-100, 106 & 107 (equivalent to the previously pending claims 25-55 & 72-104) of the present application are directed only at the embodiment shown in Figure 9.

2) In comparison to the Leahy patent, the only difference between Figure 9 of the present invention and Figure 19 of the Leahy patent is that the Leahy patent includes an adhesive whereas Figure 9 of the present application does not illustrate an adhesive (see below).



U.S. Patent No. 5,640,977

The Office takes the position that the scope of the patented claims of Leahy are so broad they also cover a surgical device and method of providing sealed access through an incision without the use of an adhesive, as is evident by the claims. For instance, independent claims 1, 20, and 28 of the Leahy patent do not recite the limitation of an adhesive. The claims of the Leahy patent only recite the adhesive in dependent claims such as claims 6, 7, and 24. The patented claims, which do not

mention the adhesive or depend upon such a claim, do not require the adhesive. Therefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate the of the present application. It is the Office's position that the claims of the present invention is directed to the same invention patentable invention lost during the interference. Since Leahy won the interference and it was ordered that the present invention is not entitled to a patent which covers the claims won by Leahy during the interference. The present invention is not entitled to a patent containing the claims corresponding to the count or counts of the interference as ordered by the Board's judgment.

Furthermore, during the interference, Appellant admitted in Appendix A of the Amendment filed on January 5, 1997 that claim 28 of the Leahy patent reads upon Fig. 9. In order to invoke the interference, on page 6 of Appendix A, Appellant compared patented claim 28 to Fig. 9 of the present application. Appellant's comparison and analysis of patented claim 28 does not indicate that the adhesive or flange is required when interpreting the scope of this claim. Thus, Appellant acknowledges that the Leahy's device can be used without an adhesive and covers the embodiment of Figure 9 of the present application.

Furthermore, claims 73-85, 87-100, 106 & 107 (equivalent to the previously pending claims 25-55 & 72-104) are directed to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count, since one skilled in the art would have recognized use of the device as set forth in the count would have



resulted in the method steps of the newly presented method claims. It is obvious to one having skill in the art that in order to provide a sealed access through an incision one must perform the claimed step of "making an incision in a patient" as well as the step of "providing a surgical device....." followed by the step of "inserting an object through an entry seal assembly coupled to the surgical device" as recited by the claims. The specific structure of the surgical device, as recited in the claims, is taught by Leahy. As a result, the method as claimed would have been obvious when one of ordinary skill used the device of Leahy.

In comparison to the Leahy patent, note that figure 19 in Leahy discloses a protector or tubular member (262) that is equivalent or an obvious variant of the claimed diaphragm, that has a distal and proximal end; the proximal end has ring that is an incision engaging portion (263) and a distal or outer ring (264). The sleeve (102) is a flexible gas-impermeable material that is closed at a distal end and open at a proximal end to receive a surgeon's hand or a surgical instrument through opening (114) of said sleeve. This sleeve has an opening (105) connected to the Distal ring (264) of the diaphragm and is seen to be equivalent to the claimed "entry seal assembly" as Leahy teaches that there is a controlled pressurized environment.

It is the position of the examiner that the Leahy device since the adhesive attachment of a drape to the coupler & to the body of the patient are not required by the invention but are merely an option for the surgeon or surgical team to have. Therefore, the engagement of the incision engaging portion to the incision & the outer engaging ring portion can be the only or "primary" coupling of the device to the skin since the

Leahy reference discloses that the drape & adhesive-backed structures of one embodiment of the device. In column 7, lines 17-20, it is stated that "Following incision, but before using the apparatus, ring (263) is inserted through the incision, and flange (111) is adhesively attached to a drape." This is a teaching that the body of the drape is not required to attach or couple the protector to the incision, but rather a teaching that the protector is capable of being used without the drape & would therefore be the only coupling to the patient. Also, it is stated in the disclosure of Leahy in column 7, lines 35-39, it states: "Additionally, or alternatively, an adhesive-backed flange may be placed around the exit opening of the sleeve, and in some cases adhesive may be applied to the patient around the area of the incision where the sealing flange is to be attached."

**Claims 73-85, 87-100, 106 & 107 are finally rejected under 35 U.S.C. 102(g) over the sole lost count of Patent Interference No. 104,195.**

Claims 73-85, 87-100, 106 & 107 correspond to the subject matter of the sole count of Patent Interference No. 104,195, as to which a judgment adverse to the applicant has been rendered. A losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992); *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985). See also MPEP §2308.03.

This rejection incorporates the principles of res judica and collateral estoppel as the independent claims are rejected as not patentably distinct from the subject matter of the lost count.

Appellant lost on priority for a count drawn to subject matter to a surgical device for providing sealed access through an incision in a patient. The Board's judgment automatically disposed of all of the applicant's claims corresponding to the count. Appellant's filing of a continuing application with claims 73-85, 87-100, 106 & 107 (equivalent to the previously pending claims 25-55 & 72-104) to the subject matter to a surgical device for providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference.

Further, Appellant's claim(s) was held unpatentable during the interference. Appellant could have moved, but did not move, to amend the claim(s). Now, Appellant has filed a continuing application with amended claims. The subject matter of the amended claims would have been anticipated or obvious in view of the sole count of the interferences and the claims must be rejected as procedurally estopped. Whether the amendment is sufficient to overcome the ground for unpatentability or not, the time to have amended the claim(s) was during the interference.

Appellant lost on priority for a count drawn to subject matter to a surgical device for providing sealed access through an incision in a patient. The Board's judgment automatically disposed of all of the applicant's claims corresponding the count. Appellant's filing of a continuing application with claims 73-85, 87-100, 106 & 107 (equivalent to the previously pending claims 25-55 & 72-104) to the method of providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference. Appellant's filing of a continuing application with claims 73-85, 87-100, 106 & 107 (equivalent to the previously pending

claims 25-55 & 72-104) to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count. The claims must be rejected as estopped on the merits by the applicant's loss in the interference, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims.

Furthermore, no second interference should occur between the same parties on patentably indistinct subject matter. If the Board of Patent Appeals and Interferences held that there is no interference-in-fact between the parties for the subject matter of the count, that holding may not be reopened in further examination. If a party that lost the earlier interference is again claiming the same invention as the count, the interfering claims should be rejected as estopped. See also MPEP §2308.03(c).

#### **(10) Response to Argument**

##### **A. Response to Appellant's argument to the rejection of the claims under 35 U.S.C. § 112, first paragraph.**

Appellant's argument is that Appellant was in possession of the claimed subject matter recited in the claims at the time the application was filed referring to Fig. 9 illustrating the device and the paragraph bridging pages 9 and 10 of the specification.

While Appellant has pointed to page 9, line 27 through page 10, line 4 and Figure 9 of the specification and drawings for the support of the new claim limitations,

the examiner respectfully disagrees that these eleven lines & Figure 9 can be interpreted to provide support for the following structures & claimed functions:

In claims 106, the limitation of an entry seal assembly located ***such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases in pressure within the controlled pressurized environment*** is not supported.

In claim 107, the limitation of the engagement of the distal ring to the internal body tissue providing ***a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment*** is not supported.

The cited paragraph and figure merely disclose a sealing means that has a diaphragm that extends from ring (61) and ends at inner ring (63), where the diaphragm is attached to a sleeve and is engaged to tissue of the body through the incision. There is a controlled pressure environment disclosed ***in the sleeve (2)*** (emphasis added that is within the sleeve- see line 4, page 10). Appellant's argument that the claimed limitations "***such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases in pressure within the controlled pressurized environment***" and "providing ***a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the***

***internal portion of the tubular diaphragm is subject to the controlled pressurized environment”*** as is claimed is well outside this disclosure of the original specification.

**B. Response to Appellant’s argument to the rejection of the claims under 35 U.S.C. § 102(e) to Leahy.**

Appellant argues that Leahy fails to disclose or suggest an entry seal assembly located proximal the tubular diaphragm, the “entry seal assembly configured to maintain a controlled pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment” of claim 106. Appellant also argues that Leahy fails to disclose or suggest “an entry seal assembly located proximal the tubular diaphragm and configured to maintain a controlled pressurized environment inside the surgical device, the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is subject to the controlled pressurized environment” of claim 107. Appellant argues the relying on Leahy to anticipate the claims to cover the embodiment of Figure 9 based upon the Interference No. 104,195 is irrelevant to the anticipation analysis.

The examiner respectfully disagrees. It is the position of the examiner that the device of Leahy does in fact provide a single coupling with the patient’s body through the incision of only the ring and diaphragm as shown below in figure 19 (see body of 102 (e) rejection below). The adhesive layer in the Leahy device is not part of the

coupling device nor is it needed for attaching the coupling to the body; it is taught to attach the surgical device to a drape (shown as D in figure 19). Further, Appellant's claim construction includes the transition phrase "comprising" which is an open-ended limitation. Thus, the inclusion of the adhesive attaching a drape to a patient is not precluded from the claim construction of the pending claims. In comparison to the Leahy patent, note that figure 19 in Leahy discloses a protector or tubular member (262) that is equivalent or an obvious variant of the claimed diaphragm, that has a distal and proximal end; the proximal end has ring that is an incision engaging portion (263) and a distal or outer ring (264). The sleeve (102) is a flexible gas-impermeable material that is closed at a distal end and open at a proximal end to receive a surgeon's hand or a surgical instrument through opening (114) of said sleeve. This sleeve has an opening (105) connected to the Distal ring (264) of the diaphragm and is seen to be equivalent to the claimed "entry seal assembly" as Leahy teaches that there is a controlled pressurized environment. Further, there must be some degree of pressure controlled to perform the medical procedure when using the device of Leahy.

It is the position of the examiner that the Leahy device having an adhesive attachment of a drape to the coupler & to the body of the patient are not required by the invention but are merely an option for the surgeon or surgical team to have. Therefore, the engagement of the incision engaging portion to the incision & the outer engaging ring portion can be the only or "primary" coupling of the device to the skin since the Leahy reference discloses that the drape & adhesive-backed structures of one embodiment of the device. In column 7, lines 17-20, it is stated that "Following incision,

but before using the apparatus, ring (263) is inserted through the incision, and flange (111) is adhesively attached to a drape." This is a teaching that the body of the drape is not required to attach or couple the protector to the incision, but rather a teaching that the protector is capable of being used without the drape & would therefore be the only coupling to the patient. Also, it is stated in the disclosure of Leahy in column 7, lines 35-39, it states: "Additionally, or alternatively, an adhesive-backed flange may be placed around the exit opening of the sleeve, and in some cases adhesive may be applied to the patient around the area of the incision where the sealing flange is to be attached." Further, Appellant notes in the instant application disclosure that the disclosed device may be attached to the body of a patient by a technique that is similar to attaching a colostomy bag where the "annular, adhesive coated flange is applied to a patients skin such that the annulus encircles the access incision" and further that the "Adhesion may be assisted by the application of an adhesive surgical drape prior to making the incision" (see page 11, lines 3-8).

**C. Response to Appellant's argument to the rejection of the claims under 35 U.S.C. § 102(g).**

Appellant argues that interference estoppel is not applicable against the claims since 1) the claims are argued to be patentably distinct from the sole lost count of the Patent Interference No. 104,195 and 2 ) Appellant is not seeking relief that could have been sought in the interference, and thus estoppel does not apply.



As previously set forth, Appellant argues that the pending claims are not estopped under 37 CFR 41.127(a)(1). The examiner respectfully disagrees. Appellant's filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the method of providing sealed access through an incision in a patient must be rejected as estopped on the merits by the applicant's loss in the interference. Appellant's filing of a continuing application with claims 26-40, 42-55 and 73-85, & 87-110 (equivalent to the previously pending claims 25-55 & 72-104) to the subject matter the method of providing a surgical device for providing sealed access through an incision in a patient would have been obvious in view of the subject matter of the count. The claims must be rejected as estopped on the merits by the appellant's loss in the interference, since one skilled in the art would have recognized use of the device as set forth in the count would have resulted in the method steps of the newly presented method claims. As previously noted in the rejections of record, the position of the examiner is that the device of Leahy is a "single" coupling assembly and as such the claims of the instant application would have been supported by the disclosure of Leahy.

Appellant further argues an entitlement to the priority date of at least Irish Patent Application No. 930649. The examiner respectfully disagrees. The Board of Patent Appeals and Interferences held that as a matter of law, the Party Bonadio, et al. is not entitled to the benefit of priority in their U.S. application of the earlier filed Irish applications an the PCT applications, because the current named individuals, Bonadio

and Reid, are not the same inventive entities as the individuals named in Party Bonadio et al.'s Irish and PCT priority applications. According to §201.15 of the MPEP:

"The foreign application may have been filed by and in the name of the assignee or legal representative or agent of the inventor, as applicant. In such cases, if the certified copy of the foreign application corresponds with the one identified in the oath or declaration as required by 37 CFR 1.63 and no discrepancies appear, it may be assumed that the inventors are entitled to the claim for priority. If there is a disagreement as to inventors on the certified copy, the priority date should be refused until the inconsistency of disagreement is resolved." [Emphasis added]

See Motion under 37 C.F.R. 1.633(g) in Interference No. 104,195.

Appellant's arguments under this section of the response are not persuasive. First, applicant notes that "to the extent that the withholding of the priority date being based upon estoppel, Appellant showing of non-obviousness over Leahy renders the basis moot". Indeed if Appellant were claiming a novel and non-obvious variation of the invention defined by the count of the lost interference preceding, the question of propriety of the priority claim would be viewed in a different light. However, as noted in the office action, the Office is not persuaded of non-obviousness over Leahy and the lost count; thus the basis is not moot.

Next, Appellant submits In re Deckler (citation omitted) does not support withholding the priority date of the '649 application as the sole issue in Deckler, in applicants view, was whether the losing party in an interference proceeding is entitled to

a patent covering claims the party admits are patentable indistinguishable from the claims involved in the interference. Here, Appellant does not admit the claims are patentably indistinguishable but asserts patentable distinctness. Further Appellant argues Deckler deals with preclusion as to claims and is silent as to preclusion as to priority under 35 USC 119(d). The examiner is not persuaded. In re Deckler stands for the proposition that a losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. Patentable distinctness of the instant claims from the lost count has not been established by Appellant: thus the estoppel rejection has been maintained herein. Preclusion as to claims includes the preclusion as to priority under 35 USC 119 as the claims lost in the prior interference were not accorded the priority date. The same claims here can not be granted an older date in order to overcome a rejection based upon the patent of the winning party to the interference. In addition, it is noted that procedural estoppel also applies here in that a losing party is procedurally barred from seeking from the examiner relief that could have been – but was not – sought in the interference proceeding. 37 CFR 41.127(a)(1). Appellant did not challenge the determination that he was not entitled to the priority in the prior interference. In this inaction, future answers to this issue are waived. The time to flush out the issue of priority, with respect to the date of invention of the subject matter covered by and corresponding to the count awarded to Leahy, has past. Appellant can not circumnavigate the prior proceeding resolution by the filing of a continuation and asserting the priority when the same invention is being claimed. The winning party of a

prior interference must be able to have confidence in the outcome of the proceeding and Appellant's failure to take action, respond to, or appeal the prior decision/judgment in interference can not be overlooked herein.

Finally, Appellant argues the decision to deny applicant's right to the priority date under 35 USC 119(d) came in the form of a decision on a preliminary motion and is not a final judgment for res judicata or estoppel purposes. In support applicant cites *Curtis Mfg. Co. Inc. v. Plasti-Clip Corp.*, 933 F. Supp. 94, 103 (D. N. H. 1995). No copy of this decision was provided by applicant and the only references the examiner sees by searching the USPQ of this citation appear unrelated.<sup>123</sup> Thus the examiner is unable to determine precisely Appellant's position any deeper than the general principle that a decision on preliminary motion is not a final judgment. In response, in general the examiner notes decisions on motions become final when they are unchallenged or the challenges found unpersuasive. The final judgment as to the issue of priority in the prior

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<sup>1</sup> As cited in *Flex Products Inc. v. BASF Corp.*, 47 USPQ2d 1380 (E.D. Mich. 1998) "Indeed, one court has gone so far as to suggest that attorney opinions in such cases may be "withh [e]d until trial." *Curtis Mfg. Co. v. Plasti-Clip Corp.*, 933 F.Supp. 107, 118 (D.N.H. 1995), *rev'd on other grounds*"

<sup>2</sup> As cited in *Heidelberg Harris Inc. v. Loebach*, 46 USPQ2d 1948 (Fed. Cir. 1998) "Loebach attempts to distinguish *Arachnid* by arguing that the district court in that case did not actually rescind the original assignment, but merely ordered the patent to be assigned to *Arachnid*. We do not agree with Loebach's characterization of that case. The district court in *Arachnid* declared *Arachnid* "to have been" the owner of the invention from the outset, yet this court nonetheless rejected *Arachnid*'s argument that it was entitled to sue for infringement during the period before it obtained record title to the patent. *Id.* at 1579, 19 USPQ2d at 1517; see also *Curtis Mfg. Co. v. Plasti-Clip Corp.*, 933 F.Supp. 94, 101-02 (D.N.H. 1995)."

<sup>3</sup> As cited in *J. & J. Manufacturing Inc. v. Logan*, 48 USPQ2d 1412 (E.D. Tex., 1995) "However, in *Curtis Manufacturing Co., Inc. v. Plasti-Clip Corporation*, the United States District Court of New Hampshire looked the *Arachnid* loophole squarely in the eye (even though jurisdiction was not in question). 933 F.Supp. 94 (D.N.H. 1995). There, the manufacturer of a plastic clip document holder device brought an action against its competitors for patent infringement, fraudulent procurement of patent, and various common-law tort claims. *Id.* In their final pretrial statement the plaintiffs indicated that if the patent in issue was indeed assigned to them, then they would seek damages for the time period which the defendant held legal title to the patent." And "*Curtis*, 933 F.Supp. at 101-102 (D.N.H. 1995) (emphasis added)." Also referenced "It is worth noting that the district court was reviewing a patent interference action previously brought in the Patent and Trademark Office; and, as a result of this procedural posture, jurisdiction in the federal court was not at issue."

interference proceeding was awarded to the senior party and not to Appellant. Absent further precedent to the contrary from applicant, the argument is unpersuasive.

**(11) Related Proceeding(s) Appendix**

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Patricia Bianco

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772

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